



**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/893,759	07/11/97	SAITOH	K 1587-0024-0

022850 HM22/0607  
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EXAMINER

CHIN, C

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

*20*  
06/07/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**08/893,759**

Applicant(s)  
**Saitoh et al**

Examiner  
**Chris Chin**

Group Art Unit  
**1641**



☒ Responsive to communication(s) filed on Apr 13, 1900

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 7-34 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 7-34 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on 4/13/00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/893,759 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Claim Rejections - 35 U.S.C. § 112***

2. Claims 7-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 21 are vague. These claims lack a correlation step that relates the detected agglutinate to the presence of antigen in the sample being assayed as recited in the preamble of the claims. These claims are further vague because it is not clear as to what the antibody not having strict specificity for the antigen is also specific for. The language “does not have strict specificity for the antigen” that has been inserted into these claims suggests that one of the antibodies can bind to the antigen that is to be detected and/or to some other antigen that is not defined in the claims.

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***Claim Rejections - 35 U.S.C. § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 7, 10-13, and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Strahilevitz (U.S. Patent 4,375,414) for the reasons of record in paper 12.

In response to this rejection, Applicants argue that Strahilevitz fails to disclose using one antibody having high specificity for the antigen that is to be detected while the other antibody does not have strict specificity for the antigen that is to be detected.

Applicant's arguments have been considered but are not convincing. The new limitation added to claim 7 stipulates that one of the antibodies does not have strict specificity for the antigen which is interpreted to mean that the antibody does bind to the antigen. And in view of the 112 second paragraph rejection, it is not clear as to what else this antibody binds to. Thus, it would appear that the Strahilevitz reference still anticipates the claimed invention.

5. Claims 21-27 and 29-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim GMBH (EP 617 285 A2) for the reasons of record in paper 12.

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In response to this rejection, Applicants argue that EP 617 285 A2 fails to disclose using one antibody having high specificity for the antigen that is to be detected while the other antibody does not have strict specificity for the antigen that is to be detected.

Applicant's arguments have been considered but are not convincing. The new limitation added to claim 21 stipulates that one of the antibodies does not have strict specificity for the antigen which is interpreted to mean that the antibody does bind to the antigen. And in view of the 112 second paragraph rejection, it is not clear as to what else this antibody binds to. Thus, it would appear that the EP 617 285 A2 reference still anticipates the claimed invention.

***Claim Rejections - 35 U.S.C. § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahilevitz for the reasons of record in paper 12.

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8. Claims 7-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Cragle et al (WO 85/02258) in view of Strahilevitz (U.S. Patent 4,375,414) and Boehringer Mannheim GMBH (EP 617 285 A2) for the reasons of record in paper 12.

In response to this rejection, Applicants argue that Cragle et al, Strahilevitz, EP 617 285 A2 all fail to disclose using one antibody having high specificity for the antigen that is to be detected while the other antibody does not have strict specificity for the antigen that is to be detected.

Applicant's arguments have been considered but are not convincing. The new limitation added to claims 7 and 21 stipulate that one of the antibodies does not have strict specificity for the antigen which is interpreted to mean that the antibody does bind to the antigen. And in view of the 112 second paragraph rejection, it is not clear as to what else this antibody binds to. Thus, it would appear that the claimed invention is still made obvious by the combined teachings of Cragle et al, Strahilevitz, EP 617 285 A2.

### ***Conclusion***

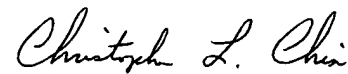
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 9:30 am to 7:00 pm. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc  
June 5, 2000



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800-1641